IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK
(ROCHESTER DIVISION)

MEGAN HOLVE, individually and on behalf of all others similarly situated, Plaintiff, -vs.- MCCORMICK & COMPANY, INC., a Maryland Corporation, Defendant.	Case No. 6:16-cv-06702(FPG) **JOINT STATUS REPORT**

I. INTRODUCTION

On August 14, 2018, this court issued a decision and order resolving Defendant McCormick & Company, Inc.'s ("Defendant" or "McCormick") motion to dismiss the complaint of Plaintiff Megan Holve ("Plaintiff") or, in the alternative, stay the action pending "the Food and Drug Administration's ('FDA') rulemaking concerning the use of the term 'natural' on food labeling and the United States Department of Agriculture's ('USDA') rulemaking concerning labeling of bioengineered foods. Dkt. No. 17 (the "Decision") at 1.

In its Decision, the Court granted McCormick's motion to dismiss in part, denied it in part, and stayed Plaintiff's remaining claims pursuant to the primary jurisdiction doctrine pending "the FDA's ongoing rulemaking process regarding 'natural' food labeling." *See id.* at 31-34 (primary jurisdiction analysis). The Court did not address whether a stay would be warranted based on the USDA rulemaking. *Id.* at 34 n.14. The Court further ordered that, by February 1, 2019, the parties should submit "a joint status report with any material updates on

the FDA and USDA rulemaking processes and their respective positions on lifting the stay." *Id.* at 35. Consistent with that direction, the parties respectfully submit the below updates.

II. UPDATES ON THE FDA AND USDA RULEMAKING PROCESSES.

FDA. In a December 19, 2018 update letter regarding that rulemaking, FDA Commissioner Scott Gottlieb "recognize[d] this is an important matter for consumers and the food industry." *See* Exhibit A at 1.[1] The letter noted that the FDA "received and reviewed more than 7,600 comments" during its notice-and-comment period (*id.*), and was "actively working on this issue." *Id.* Commissioner Gottlieb added that the "FDA recognizes that there are widespread differences in beliefs regarding what criteria should apply for products termed 'natural'" (*id.*), and indicated that the FDA was working to balance those various views.

Commissioner Gottlieb concluded by stating that "in 2019, FDA plans to publicly communicate next steps regarding Agency policies related to 'natural.'" *Id.*

USDA. On December 21, 2018, the USDA's Agricultural Marketing Service ("AMS") promulgated its final rule establishing a new national mandatory bioengineered ("BE") food disclosure standard (the "NBFDS"). 83 FR 65814 (the "Final Rule"). The new rule becomes effective as of February 19, 2019. *Id.*

III. THE PARTIES' POSITIONS ON LIFTING THE STAY.

Plaintiff's Position.

Plaintiff submits that the stay should be lifted so that the case can proceed on the merits. Despite informal statements made by FDA Commissioner Scott Gottlieb over the past 3 years that "natural" rulemaking is forthcoming, the FDA has taken no official action, and NBFDS development has no bearing on Plaintiff's claims.

[1] Commissioner Gottlieb's letter is also available on the public docket of another case involving the term "natural" that has been stayed pending FDA rulemaking. *See In re Kind LLC "Healthy and All Natural" Litig.*, No. 15-md-2645-WHP (S.D.N.Y.), at Dkt. No. 138 (December 20, 2018).

As previously briefed in Plaintiff's Opposition to Defendant's Motion to Dismiss (ECF No. 100), the NBFDS does not apply to this case because Plaintiff does not allege Defendant should have disclosed that the Products contain bioengineered ingredients. Rather, Plaintiff alleges that the Products affirmatively claim to be "Natural" when they are not. Plaintiff's claims are about the misleading information Defendant affirmatively chose to print on to its labels, not its failure to affirmatively disclose GMO information

Efficiency is the deciding factor in whether to invoke primary jurisdiction. Several courts have lifted stays or refused to grant them in cases such as this one, noting the lengthy amount of time the FDA has had, but failed to enact new "Natural" rules, and highlighting the uncertainty of when, if ever, the FDA will be enacting such rules.[2]

Moreover, in the unlikely scenario that the FDA issues new rules on "Natural" labeling, it will not dispose of the issues in this case. While labeling of "natural" foods is within the FDA's discretion, should it choose to exercise it, ultimately, a future "natural" labeling standard will not conclusively dispose of whether a reasonable consumer would have been deceived by Defendant's "All Natural" misrepresentation. *See de Lacour v. Colgate-Palmolive Co*., No. 16-8364, 2017 WL 6550690, at *4 (S.D.N.Y. Dec. 22, 2017) ("Moreover, the relative benefit of any ultimate decision [by the FDA on the use of the term "natural"] -- which will likely be relevant only by analogy to this case -- is not worth the potential wait."); *See Burton v. Hodgson Mill, Inc.*, No. 16-1081, 2017 WL 1282882, at *8 (S.D. Ill. Apr. 6, 2017) ("Defendant argues that this Court should stay this case under the doctrine of primary jurisdiction because the FDA may be in

[2]. *See, e.g.*, *Forsher v. Boar's Head Provisions Co., Inc.,* No. 17-cv-04974-CW, Dkt. 41 (N.D. Cal. Sept. 14, 2018) (denying stay on the basis that staying the case could last for a lengthy and indefinite period absent FDA developments)(attached as Exhibit B); *Chavez v. Church & Dwight Co., Inc.*, No. 17-c-1948, 2018 WL 2238191, at *9 (N.D. Ill. May 16, 2018) (declining to issue stay based on the primary jurisdiction of the FDA "given the uncertainty and the likely prejudice [plaintiff] would face if granted.").

the process of formulating a more concrete definition of the term 'all natural.' The Court is not persuaded by this argument for numerous reasons, including because the FDA last issued a call for proposals on the topic in the fall of 2016 and has not yet issued any further timeframe or next steps.").

The FDA's public comment period on the rules regarding the use of the term "natural" on food labels closed on May 10, 2016, well over two years ago. Since that time, the FDA has not promulgated any such rules, nor has it given anything beyond the vaguest indications that it is even considering doing so.

Defendant's Position. McCormick respectfully submits that, for the reasons explained in its prior briefing and in the Court's Decision, the stay should be maintained until the FDA's ongoing rulemaking process is complete. McCormick thus requests that the Court's current stay be extended, and that the parties be directed to file a further joint status report no later than: (1) two weeks after the FDA communicates its next steps in the rulemaking process or (2) August 1, 2019, whichever is earlier.

That is precisely how Judge White of the United States District Court for the Northern District of California recently chose to proceed in *Rosillo v. Annie's Homegrown, Inc.*, No. 17-cv-2474-JSW (N.D. Cal.), a putative consumer class action challenging "natural" labeling on food products. Specifically, Judge White extended a prior stay based on the primary jurisdiction doctrine (Dkt. No. 55, attached as Exhibit C) in light of Commissioner Gottlieb's December 2018 letter, which "made some indication that the regulatory process is close to completion." *Id.* at 2. Judge White explained that "given the FDA's telegraphing (to a member of Congress, no less) impending developments in 2019 . . . it is wise to await the FDA's heralded potential guidance." *Id.* Concluding that "it would not be prudent to lift the stay at this time" (*id.*), Judge

White ordered the parties to provide a further status update consistent with the schedule proposed above. *Id.*

McCormick respectfully submits that the same analysis applies here. The Court has already "join[ed] the growing number of courts who have deferred to the FDA's expert and specialized knowledge on the subject, and [chosen to] await pertinent guidance on the permissible uses of the term 'natural' in food labeling." Decision at 33 (quoting *Scholder v. Riviana Foods Inc.*, No. 16-cv-6002(ADS)(AKT), 2017 WL 2773586, at *3 (E.D.N.Y. June 23, 2017)). That reasoning still holds, particularly given Commissioner Gottlieb's recent confirmation that the FDA's rulemaking remains underway and that the FDA will provide further updates in 2019. *See supra* at 2. Commissioner Gottlieb's letter also indicates that the FDA's continued work involves balancing the competing interests of various stakeholders in "natural" labeling. *Id.* That policy-laden process falls "particularly within the agency's discretion," *Ellis v. Tribune Television Co.*, 443 F.3d 71, 82 (2d Cir. 2006), confirming the propriety of continued deferral to the FDA. *See* Decision at 32-33; *see also Kind I*, 209 F. Supp. 3d 689, 695 (S.D.N.Y. 2016) ("[T]he issue of whether the particular ingredients referenced in the Complaint rendered the 'all natural' label misleading seems to be particularly within the FDA's discretion.").[3]

[3] Because a stay remains appropriate based on the FDA's ongoing rulemaking process, the Court again need not consider whether the USDA's rulemaking with respect the NFBDS would justify a stay. *See* Decision at 34 n.14.

However, the Court should be aware that the Final Rule provides that a food product is not a bioengineered, or BE, food for purposes of the Final Rule's disclosure regime unless the food contains *detectable* level of *modified* DNA. Specifically, the Final Rule defines a BE food as, in relevant part, "food that *contains genetic material that has been modified* through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature." 7 C.F.R. § 66.1 (emphasis added). The same subsection also provides that this modified DNA must be "detectable" as provided elsewhere in the Final Rule. *Id.* As alleged, none of the ingredients identified in Plaintiff's complaint are BE foods to which any disclosure obligation attaches. Citric acid (Compl. ¶ 50) is not a BE food because any BE inputs used in the fermentation process, such as maize or glucose, would be consumed during fermentation and would thus be considered incidental additives, rendering them exempt from disclosure. 7 C.F.R. § 66.1; *see also* 21 C.F.R. § 101.100(a)(3) (defining incidental additives as those present in food at an insignificant level and that have no

Finally, the requested extension of approximately six months is a "stay of limited duration" (Decision at 34). Given Commissioner Gottlieb's recent comments, there is every reason to think that the Court and the parties will receive further guidance from the FDA within that window. Moreover, as the Court has already observed, "[t]he Second Circuit . . . has 'cautioned against' weighing potential delay as a relevant factor" in these circumstances. Decision at 34 (citing *Kind I*, 209 F. Supp. 3d at 696 (citing *Tassy v. Brunswick Hosp. Ctr., Inc.*, 296 F. 3d 65, 68 n.2 (2d Cir. 2002))). Finally, as the current process illustrates, the parties can always reevaluate the need for any continued extension later in 2019 as needed.

technical or functional effect in the food). As for corn starch and white corn flower (Compl. ¶ 49), those ingredients would only be subject to disclosure to the extent they contain detectable levels of modified DNA – and the complaint is silent on whether any testing was done to detect the presence of modified DNA.

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Respectfully submitted,

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